Criteria for Use
Dalfampridine (Ampyra®)
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VHA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives and MSCoE Directors

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services.

The Product Information should be consulted for detailed prescribing information. The VA National PBM-MAP-VPE Dalfampridine Drug Monograph for Ampyra™ are available at www.pbm.va.gov or http://vaww.pbm.va.gov for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive dalfampridine*

□ Moderate to severe renal impairment (CrCl<50 ml/min)

□ Previous or current history of a seizure disorder

□ Unstable disease at the time of initiation (ie; dose change in DMARD therapy within the past month or evidence of relapse in the past month)

Inclusion Criteria *The answers to all of the following must be fulfilled in order to meet criteria.*

☐ Diagnosis of MS made by a VA neurologist, or locally designated MS expert.

☐ Documented difficulty with walking as defined by a functional measure (e.g.; Timed 25 Foot Walk Test, MSWS-12 http://jnnp.bmj.com/content/74/suppl_4/iv22/T2.expansion.html, Subject/Caregiver Impression of Change, Clinician Impression of Change, etc) which will be repeated to establish treatment response.

Establishing Treatment Response/Renewal Criteria

- Because fewer than 50% of MS patients respond to therapy and therapy has risks, a 2 to 4 week trial of therapy should be used prior to beginning ongoing therapy.
- The patient should be evaluated prior to therapy and then after 2 to 4 weeks to determine whether objective improvements which justify continued therapy are present.

Issues for Consideration

- Dalfampridine is available via the non-formulary process at the facility level
- In patients with mild renal impairment (CrCl 51-80 mL/min), the blood levels of dalfampridine may reach levels associated with increased seizure risk. Therefore for patients with mild renal impairment, the use of dalfampridine requires careful consideration of the potential benefits of treatment as well as the potential risk of seizure. It is suggested that renal function be assessed annually.
- Dalfampridine can increase the risk of seizures; caution should be exercised when using concomitant drug therapies known to lower the seizure threshold.
- Use in Spinal Cord injury patients is not supported by robust evidence and should be evaluated on a case by case basis. Please refer to the monograph for a discussion of the available evidence.